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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,889	02/21/2001	Earl R. Owen	12724-002001	6045

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Fish & Richardson
Suite 500
4350 La Jolla Village Drive
San Diego, CA 92122

EXAMINER

CHISM, BILLY D

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 01/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/719,889

Applicant(s)

OWEN ET AL.

Examiner

B. Dell Chism

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 19-22 and 24-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11-16, 19-22, 24-26, 32-38, 45-48, 52 and 53 is/are allowed.
- 6) ☒ Claim(s) 1-10, 27-31, 39-44, 49-51, 54 and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

This office action is in response to Applicants' response filed 15 September 2003.

Withdrawal of Objections and Rejections

The rejections and/or objections made in the prior office action, which are not explicitly stated below, in original or modified form are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Applicants' arguments filed 15 September 2003 will be addressed to the extent that they pertain to the present grounds of rejection.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. (Necessitated by Amendment) Claims 1 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The broad-brush discussion of making substances that serve as possible proteinaceous solders does not constitute a disclosure of a representative number of members of that class. No representative number of claimed solders was disclosed that would lend a full description to the entire class that is entailed by the instant claim 1. No other class members were shown to

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possess the necessary physical properties required to perform as a constituent to a proteinaceous solder as claimed. The specification's general discussion of making proteinaceous solders constitutes an invitation to experiment by trial and error. Such does not constitute an adequate written description for the claimed substances. Putting the claimed methods into practice awaited someone actually discovering a necessary component of the invention. Without the substances called for in the methods, Applicant could no more be said to have possessed the complete claimed invention. While the specification identifies some broad categories of compounds that might work, these descriptions, without more precise guidelines, amount to little more than, "a starting point, a direction for further research." *Genentec, Inc. V. Novo Nordisk A/S*, 108 F.3d 1361, 1366, 42 U.S. PQ.2d (BNA) 1001, 1005 (Fed. Cir. 1997).

Furthermore, the courts have held that even though a specification is enabling for the practice of an entire class by one of skill in the art, the specification does not necessarily afford full written description of the entire class as claimed, . Application of DiLeone 436 F.2d 1404 (1971).

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. (Maintained) Claims 31 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, wherein the claims recite the indefinite phrase "or an analogue thereof." A protein analogue does not necessarily have to be a protein and since the solder requires a proteinaceous substance, there cannot be just an analogue thereof. Furthermore, it is unclear as what the metes and bounds of the limitation are regarding the analogues thereof.

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5. (Necessitated by Amendment) Claims 2-10, 27-31, 40-44, 49-51 and 54-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are rejected for depending from rejected claims.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. (Necessitated in part by Amendment) Claims 1-7, 27-31, 43-44 and 49 rejected under 35 U.S.C. 102(e) as being anticipated by Lauto *et al.* (U.S. Patent No. 6,323,037).

The examiner acknowledges Applicants' traversal of Lauto *et al.* in the previous office action, and the examiner acknowledges that Lauto *et al.* does not teach the denatured biomolecular solder as is explained in Applicants' response. However, the biomolecular solder of claim 1 that comprises a proteinaceous substance is not further limited by the incorporation of a method of making the biomolecular solder. Claim 1 is a product-by-process claim, thus, the recitation of the method of making the biomolecular solder comprising a proteinaceous substance is not considered as a limitation to the product of claim 1. Without the method of making limitation in amended claim 1, the claim only recites a biomolecular solder comprising a proteinaceous substance, which is taught by Lauto *et al.* Subsequent dependent claims remain rejected for the reasons set forth in

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the previous office action. Lauto *et al.* teaches a biomolecular solder comprising a protein that can be albumin, with a dye comprising indocyanine green or methylene blue, with and adjuvant such as a growth factor, and wherein the solder is preformed.

Conclusion

8. Claims 11-16, 19-22, 24-26, 32-38, 45-48 and 52-53 are free of the prior art. Claims 1-10, 27-31, 43-44, 49-51 and 54-55 are rejected.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone number for the

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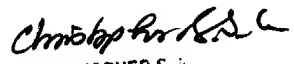
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organization where this application or proceeding is assigned is 703-872-9306 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

B. Dell Chism
23 December 2003


CHRISTOPHER S. L.
SUPERVISORY PATENT L.
TECHNOLOGY CENTER 1600